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10/725,304	12/01/2003	Lars Lindberg	P03,0559	2896

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SCHIFF HARDIN & WAITE
Patent Department
6600 Sears Tower
233 South Wacker Drive
Chicago, IL 60606

EXAMINER	
ALI, SHUMAYA B	
ART UNIT	**PAPER NUMBER**
3771	

MAIL DATE	DELIVERY MODE
03/31/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/725,304	LINDBERG ET AL.	
	Examiner	Art Unit	
	SHUMAYA B. ALI	3771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12/3/07*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-8* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 3-8* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *03 December 2007* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

1. In response to the office action mailed on 9/5/07, Applicant amended claims 1, 3-5, and 7, cancelled claim 3 and entered new claim 8. Currently, claims 1, 3-8 are pending in the instant application.

Oath/Declaration

2. New Oath/declaration filed on 12/18/07 is acknowledged and accepted by the Examiner.

Drawings

3. The drawings were received on 12/3/07. These drawings are not acceptable because drawing shows permeable membrane only in portion of the cuff, which is not supported by the specification as originally filed.

Specification

4. The amendment filed 12/3/07 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: "a poriton" of outward facing surface of the cuff 6 is formed of a permeable membrane 6A is new matter. Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6.

7. Claims 5 and 8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 5 line 5 and 6 the recitations of "dosing unit including said additive from said reservoir in said medicament" are confusing because it is not clear whether the medicine already contain the additive or the medicine and additive are kept separate in separate reservoirs. Specification does not clearly state how the additives are introduced in the fluid.

In claim 8 limitation in lines 1-3 are found in claim 1, thus does not further limits the parent claim.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 1, 3-5, and 8 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Kruse et al. US 5/957,839.

As to claim 1, Kruse discloses a medical device (see fig.1) comprising: a cuff (14). Although Kruse is silent on the cuff can be configured to be positioned in the endotracheal of a subject, however, Kruse in figure 1 clearly shows that his device has a tube and a cuff and the distal end of the tube containing cuff can be slide into a person's trachea and allow the person to respirate though the lumen of the tube and aperture (32) on the tube. Furthermore, Kruse in column 12 lines 2-4 discloses that the distal end of the tube/catheter is placed in the animal's stomach via the mouth, thus, suggest that the distal end containing cuff can be placed within a trachea when passed though the mouth of the subject. Kruse discloses a first tube (20) having a first end in fluid communication with an interior of the cuff (see fig.1) and having an opposite, second end (connecting 56); a second tube (22) having a first end in fluid communication with the interior of the cuff (see fig.1) and having an opposite, second end (connecting 56); a pumping device (52) connected to the respective second ends of the first and second tubes that circulates a fluid through the interior of the cuff (col.8, lines 34 and 35); and said cuff comprising a membrane (col.6, lines 30-33) that is selectively permeable to a specific substance (CO2 gas or "particular gas to be measured", see col.11 line 61) relative to said fluid, said membrane being disposed to allow transfer through said membrane of said substance from an exterior of the cuff to the interior of the cuff and an exterior of the cuff (since the membrane is permeable to gas, it will allow transfer of gas from the trachea ("exterior") to tube ("interior") via the membrane, see also col.6, lines 30-33), and analysis unit (72) in fluid communication with said flow path (see

fig.1) tat analyzes said fluid with regard to content in said fluid of said substance that has mixed with said fluid from the exterior of the cuff (see col.10 lines 63-68 and col.11 lines 1-24).

As to claim 3, Kruse discloses the analysis unit includes a calculation unit (76) that quantitatively determines an amount of said specific substance in said fluid relative to a predetermined normal amount (col.10, lines 63-68, and col.11, lines 1-24).

As to claim 4, Kruse discloses the medical device comprises a dosing unit (46) in fluid communication with said flow path that administers a dose of a medicament into said fluid (col.7, lines 43-59).

As to claim 5, Kruse discloses wherein said analysis unit includes a calculation unit (76) that quantitatively determines an amount of said substance in said fluid relative to a predetermined normal amount (see col.12 lines 30-40 where measured CO2 values are compared with a laboratory value/predetermined normal amount), dosing unit comprises at least one reservoir (a syringe inherently has a reservoir/space where gas will be held inside 46) containing at least one additive (substance introduced by the syringe) corresponding to said substance, said dosing unit including said additive from said reservoir in said medicament if said analysis unit determines that said amount of said substance in said fluid is below said predetermined normal amount (see col.9 lines 53-57).

As to claim 8, Kruse discloses 58 that measures partial pressure of CO2 at any point in circuits 22, 42, 20 (see col.10 lines 23-25), thus, when the dosing unit including said additive, the analyzing unit inherently analyzes the fluid with regard to content in said fluid of said substance that has mixed with said fluid from said exterior of the cuff and said medicament since analyzing unit would analyzed total fluid content inside the tube in order to determine CO2 concentration.

11. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kruse et al. and in view of Schultze US 4,141,364.

As to claim 6, Kruse lacks wherein said cuff comprises at least one partition wall that partition the interior of said cuff into multiple chambers. However, Schultze teaches endotracheal tube cuff with multiple chambers (see figs. 7 and 8). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Kruse in order to provide multiple chambers because it is known in the art as taught by Schultze. Kruse further lacks each chamber having a first chamber tube with a first chamber tube end in fluid communication therewith and a second chamber tube with a first chamber tube end in fluid communication therewith, and wherein said first chamber tube has a second chamber tube end and said second chamber tube has a second chamber tube end in fluid communication with said pumping device for circulation of respectively separate fluids through the multiple chambers. However, since Kruse teaches at least two tubes are in communication with the cuff at a different location within the cuff, and one end of each tube is connected to a pumping device, it would have been obvious to have each tubes of Kruse connected to separate chambers of Schultze. It would have been further obvious to have multiple tubes (i.e. first and second chamber tubes of first and second chamber as claimed) connecting to the cuff because it has been held that mere duplicate of tubes only requires routine skills in the art. Furthermore, it would have been obvious to one of ordinary skill in the art to increase the number of tubes to expedite fluid circulation within the medical device.

12. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kruse et al. and in view of Hanson et al. US 5,985,307 and in further in view of Walther et al. US 6,660,833 B1.

As to claim 7, Kruse lacks wherein said membrane is permeable to at least one protein, as said substance, selected from the group of proteins consisting of SP-A, SP-B, SP-C and SP-D that are present in surfactant. However, Hansen teaches a balloon cuff membrane device that can be used to deliver therapeutic agent in the respiratory tree (see col.2, lines 44 and 45) to treat a variety of disease syndromes (see col.18, lines 55 and 56). Although Hansen's device is permeable to protein (i.e. antibody, see col.26, line 55), Hansen however is silent on the claimed protein. However, Walther teaches respiratory distress syndrome therapy using peptide analogs of human SP-B that mimics human surfactant protein B (see abstract). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Kruse in order to provide a membrane that allowed protein to pass though in the respiratory tree for the purposes of treating respiratory disease syndrome as taught by Hansen and further modify the membrane to be selective to SP-A for the purposes of treating respiratory distress syndrome as taught by Walther.

Response to Arguments

13. Applicant's arguments filed 12/3/07 have been fully considered but they are not persuasive. On page 10 lines 1-4 Applicant argues that the cuff of Kruse can not be positioned in the trachea, however, as described in claim 1 the Kruse's cuff is capable of being positioned within the trachea. In lines 15 and 16 Applicant further argues that the "Figure of Kruse et al were inserted into the trachea of the patient, this would completely block respiration of the

patient", this argument however is not well taken because figure 1 shows distal orifices (32 and 30), which would allow respiration though the tube. On page 11 lines 15-17 Applicant argues that Kruse's cuff allows permeation in both direction, however, for claimed invention it is important "only" that the analysis unit be able to measure a substance that has entered into the interior of the cuff from the exterior". This argument is not well taken because the term "only" is not supported by the claim. Thus, amended claims as well read on Kruse.

Conclusion

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

15. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHUMAYA B. ALI whose telephone number is (571)272-6088. The examiner can normally be reached on M-W-F 9 am - 5 pm.

17. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on 571-272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

18. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Shumaya B. Ali /
Examiner, Art Unit 3771